

Genial Digital Oral Thermometer



PRODUCT INFORMATION



Digital Thermometer T15SL

Range	32.0 °C~42.9°C
Accuracy	±0.1°C, 35.5°C~42.0°C
Display	Liquid crystal display;1/3 DUTY,1/2 BIAS
Battery	One 1.5 V DC. button battery (size LR41)
Using environment	Temperature:10°C~40°C(50°F~104°F) Relative humidity:15%RH~85%RH Atmospheric pressure:86kPa~106kPa
Storage and transportation condition	Temperature:-25°C~55°C(-13°F~131°F) Relative humidity:15%RH~85%RH Atmospheric pressure:50kPa~106kPa
Applied part	Digital Thermometer surface
Mode of operation	Direct mode

GENIAL 

DIGITAL THERMOMETER

I FLEXIBLE TIP



T15SC



Waterproof



Accuracy



Rectal, Oral
and Axillary



Read °F and °C



Flexible Tip



For Babies,
Children and Adults



Can be used
for Animals



Big LCD

Establishment Registration & Device Listing

FDA Home Medical Devices Databases



New Search		Back To Search Results
Proprietary Name:	Digital Thermometer, model: T11, T11L, T12, T12C, T12D, T12E, T12L, T14, T14H, T15, T15B, T15S, T15SL, T15SC, T17; Digital Thermometer, model: T28, T25, T26; Infrared Thermometer, model: T80, T81, T82, T83, T84, T85; Infrared Thermometer, model: T90, T91, T92, T93	
Classification Name:	THERMOMETER, CLINICAL COLOR CHANGE	
Product Code:	FQZ	
Device Class:	1	
Regulation Number:	880.2900	
Medical Specialty:	General Hospital	
Registered Establishment Name:	GUANGDONG GENIAL TECHNOLOGY CO., LTD.	
Owner/Operator:	Guangdong Genial Technology CO., Ltd.	
Owner/Operator Number:	10072762	
Establishment Operations:	Manufacturer	

Page Last Updated: 05/04/2020

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English



EC Certificate Production Quality Assurance System: Certificate CN19/41108

The management system of

Guangdong Genial Technology Co., Limited

11th Road, Area B, Guangfozhao Economic Cooperation Zone, Zhagang Town, Huaiji County, Zhaoqing City, Guangdong Province, 526437, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex V

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 December 2019 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 16 September 2013 and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered CN/CAN/ 15976

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
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LPMD5006 - Certificate CE1639 Annex V_EN rev. 01

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Guangdong Genial Technology Co., Ltd.



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Certificate CN19/41108, continued

Guangdong Genial Technology Co., Limited

Directive 93/42/EEC on medical devices, Annex V

Issue 1

Detailed scope

**Digital Blood Pressure Monitor and Digital Thermometer
to measure body temperature**

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

Room 2710, 2711, 2712, No.242 Tianhe Road, Tianhe District,
Guangzhou City, Guangdong Province, 510620, P.R. China

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Certificate CN13/31126

The management system of

Guangdong Genial Technology Co., Limited

11th Road, Area B, Guangfozhao Economic Cooperation Zone, Zhagang Town,
Huajji County, Zhaoqing City, Guangdong Province, 526437, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 06 August 2019 until 16 September 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 09 August 2022
Issue 4. Certified since 16 September 2013

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by



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HC SGS 13485 2016 0118 M2

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**Guangdong Genial Technology
Co., Limited**

**ISO 13485:2016
EN ISO 13485:2016**



Issue 4

Detailed scope

**Manufacture of Digital Blood Pressure Monitors
and Digital Thermometers to measure body temperature**

Additional facilities

**Room 2710, 2711, 2712, No.242 Tianhe Road, Tianhe District,
Guangzhou City, Guangdong Province, 510620, P. R. China**



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